inspections of the laboratory on a biennial basis, to equate to the applicable CLIA requirements at §§ 493.1777. In citing deficiencies, JCAHO uses a system of weighting multiple standards that aggregate to a single grid element. This system has been somewhat modified for laboratories such that weight does not preclude laboratories from correcting any deficiencies that relate to CLIA requirements. Therefore, we have determined that JCAHO's requirements are equivalent to the requirements of this subpart.

Subpart R—Enforcement Procedures for Laboratories

JCAHO meets the requirements of subpart R to the extent it applies to accreditation organizations. JCAHO policy stipulates the action it takes when laboratories it accredits do not comply with its essential standards. When appropriate, JCAHO will deny, revoke or conditionally accredit a laboratory and report that action to HCFA within 30 days. JCAHO also provides an appeals process for laboratories that have had accreditation denied or revoked.

Some specific actions JCAHO takes in response to non-compliance or violation of essential standards include:

- When JCAHO determines that a serious risk of harm (immediate jeopardy) situation exists in a JCAHO-accredited laboratory, the laboratory must immediately correct the problem that poses the risk. Failure to do so will result in a recommendation to the JCAHO Accreditation Committee to revoke that facility's accreditation. In addition, JCAHO will notify HCFA within 10 days of this determination.
- When a ICAHO laboratory is unsuccessful in PT participation for a Federally required analyte, subspecialty, and/or specialty, the laboratory will be contacted by JCAHO and required to initiate corrective actions. Failure to submit an acceptable proficiency outlier action report (POA) may result in an unscheduled, onsite survey and limitation of the laboratory's scope of accreditation for the particular analyte, specialty, and/or subspecialty. To regain accreditation, the laboratory must provide JCAHO evidence that it has successfully participated in two consecutive PT events.

We have determined that JCAHO's laboratory enforcement and appeal policies are essentially equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

Federal validation inspections and continuing oversight of JCAHO accredited laboratories will be conducted based on the regulations at 42 CFR 493.507 and 493.509.

V. Removal of Approval as an Accrediting Organization

Our regulations at § 493.511 provide that the approval of an accreditation organization, such as that of JCAHO, may be removed by HCFA for cause, prior to the end of the effective date of approval. If it is determined that JCAHO has failed to adopt requirements that are equal to or more stringent than the CLIA requirements, or that systemic problems exist in its inspection process, a probationary period, not to exceed one year, may be given to allow JCAHO to adopt comparable requirements.

Should circumstances result in JCAHO having its approval withdrawn, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: December 1, 1994.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 94–32203 Filed 12–30–94; 8:45 am]

[BPO-129-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions— Third Quarter 1994

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice lists HCFA manual instructions, substantive and interpretive regulations and other Federal Register notices, and statements of policy that were published during July, August, and September of 1994 that relate to the Medicare and Medicaid programs. Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the Federal Register at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, we are including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this timeframe.

We are also providing the content of revisions to the Medicare Coverage

Issues Manual published between July 1 and September 30, 1994. On August 21, 1989, we published the content of the Manual (54 FR 34555) and indicated that we will publish quarterly any updates. Adding to this listing the complete text of the changes to the Medicare Coverage Issues Manual allows us to fulfill this requirement in a manner that facilitates identification of coverage and other changes in our manuals.

FOR FURTHER INFORMATION CONTACT:

Margaret Cotton, (410) 966–5255 (For Medicare instruction information) Walter Rutemueller, (410) 966–5395 (For Medicare coverage information) Pat Prete, (410) 966–3246 (For Medicaid instruction information) Michael Robinson, (410) 966–5633 (For all other information)

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Health Care Financing Administration (HCFA) is responsible for administering the Medicare and Medicaid programs, which pay for health care and related services for 36 million Medicare beneficiaries and 33 million Medicaid recipients. Administration of these programs involves (1) Providing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public; and (2) effective communications with regional offices, State governments, State Medicaid Agencies, State Survey Agencies, various providers of health care, fiscal intermediaries and carriers who process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under authority granted the Secretary under sections 1102, l871, and 1902 and related provisions of the Social Security Act (the Act) and also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish in the Federal Register at least every 3 months a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the 3-month timeframe. Since the publication of our

quarterly listing on June 12, 1992 (57 FR 24797), we decided to add Medicaid issuances to our quarterly listings. Accordingly, we are listing in this notice Medicaid issuances and Medicaid substantive and interpretive regulations published from July 1 through September 30, 1994.

II. Medicare Coverage Issues

We receive numerous inquiries from the general public about whether specific items or services are covered under Medicare. Providers, carriers, and intermediaries have copies of the Medicare Coverage Issues Manual, which identifies those medical items, services, technologies, or treatment procedures that can be paid for under Medicare. On August 21, 1989, we published a notice in the **Federal Register** (54 FR 34555) that contained all the Medicare coverage decisions issued in that manual.

In that notice, we indicated that revisions to the Coverage Issues Manual will be published at least quarterly in the **Federal Register**. We also sometimes issue proposed or final national coverage decision changes in separate **Federal Register** notices. Readers should find this an easy way to identify both issuance changes to all our manuals and the text of changes to the Coverage Issues Manual.

Revisions to the Coverage Issues Manual are not published on a regular basis but on an as-needed basis. We publish revisions as a result of technological changes, medical practice changes, responses to inquiries we receive seeking clarifications, or the resolution of coverage issues under Medicare. If no Coverage Issues Manual revisions were published during a particular quarter, our listing will reflect that fact.

Not all revisions to the Coverage Issues Manual contain major changes. As with any instruction, sometimes minor clarifications or revisions are made within the text. We have reprinted manual revisions as transmitted to manual holders. The new text is shown in italics. We will not reprint the table of contents, since the table of contents serves primarily as a finding aid for the user of the manual and does not identify items as covered or not.

III. How to Use the Addenda

This notice is organized so that a reader may review the subjects of all manual issuances, memoranda, substantive and interpretive regulations, or coverage decisions published during the timeframe to determine whether any are of particular interest. We expect it to be used in concert with previously

published notices. Most notably, those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577) and the notice published March 31, 1993 (58 FR 16837), and those desiring information on the Medicare Coverage Issues Manual may wish to review the August 21, 1989, publication (54 FR 34555).

To aid the reader, we have organized and divided this current listing into five addenda. Addendum I identifies updates that changed the Coverage Issues Manual. We published notices in the **Federal Register** that included the text of changes to the Coverage Issues Manual. These updates, when added to material from the manual published on August 21, 1989, constitute a complete manual as of September 30, 1994. Parties interested in obtaining a copy of the manual and revisions should follow the instructions in section IV of this notice

Addendum II identifies previous **Federal Register** documents that contain a description of all previously published HCFA Medicare and Medicaid manuals and memoranda.

Addendum III of this notice lists, for each of our manuals or Program Memoranda, a HCFA transmittal number unique to that instruction and its subject matter. A transmittal may consist of a single instruction or many. Often it is necessary to use information in a transmittal in conjunction with information currently in the manuals.

Addendum IV lists all substantive and interpretive Medicare and Medicaid regulations and general notices published in the **Federal Register** during the quarter covered by this notice. For each item, we list the date published, the **Federal Register** citation, the title of the regulation, the Parts of the Code of Federal Regulations (CFR) which have changed (if applicable), the agency file code number, the ending date of the comment period (if applicable), and the effective date (if applicable).

Addendum V sets forth the revisions to the Medicare Coverage Issues Manual that were published during the quarter covered by this notice. For the revisions, we give a brief synopsis of the revisions as they appear on the transmittal sheet, the manual section number, and the title of the section. We present a complete copy of the revised material, no matter how minor the revision, and identify the revisions by printing in italics the text that was changed. If the transmittal includes material unrelated to the revised section, for example, when the addition of revised material causes other

sections to be repaginated, we do not reprint the unrelated material.

IV. How to Obtain Listed Material

A. Manuals

An individual or organization interested in routinely receiving any manual and revisions to it may purchase a subscription to that manual. Those wishing to subscribe should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses:

Superintendent of Documents, U.S.
Government Printing Office, Attn:
New Order, P.O. Box 371954,
Pittsburgh, PA 15250–7954,
Telephone (202) 783–3238, Fax
number (202) 512–2250 (for credit card orders); or

National Technical Information Service, Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, Telephone (703) 487–4630.

In addition, individual manual transmittals and Program Memoranda listed in this notice can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell.

B. Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. Interested individuals may purchase individual copies or subscribe to the **Federal Register** by contacting the GPO at the address indicated above. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

C. Rulings

Rulings are published on an infrequent basis by HCFA. Interested individuals can obtain copies from the nearest HCFA Regional Office or review them at the nearest regional depository library. We also sometimes publish Rulings in the **Federal Register**.

D. HCFA's Compact Disk-Read Only Memory (CD-ROM)

HCFA's laws, regulations, and manuals are now available on CD-ROM, which may be purchased from GPO or NTIS on a subscription or single copy basis. The Superintendent of Documents list ID is HCLRM, and the stock number is 717–139–00000–3. The following material is contained on the CD-ROM disk:

- Titles XI, XVIII, and XIX of the Act.
- HCFA-related regulations.
- HCFA manuals and monthly revisions.

• HCFA program memoranda. The titles of the Compilation of the Social Security Laws are current as of January 1, 1993. The remaining portions of CD–ROM are updated on a monthly basis.

The CD–ROM disk does not contain Appendix M (Interpretative Guidelines for Hospices). Copies of this appendix may be reviewed at a Federal Depository Library (FDL).

Any cost report forms incorporated in the manuals are included on the CD– ROM disk as LOTUS files. LOTUS software is needed to view the reports once the files have been copied to a personal computer disk.

V. How to Review Listed Material

Transmittals or Program Memoranda can be reviewed at a local FDL. Under the FDL program, government publications are sent to approximately 1400 designated libraries throughout the United States. Interested parties may examine the documents at any one of the FDLs. Some may have arrangements to transfer material to a local library not designated as an FDL. To locate the nearest FDL, individuals should contact any library.

In addition, individuals may contact regional depository libraries, which receive and retain at least one copy of most Federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library

Superintendent of Documents numbers for each HCFA publication are shown in Addendum III, along with the HCFA publication and transmittal numbers. To help FDLs locate the instruction, use the Superintendent of Documents number, plus the HCFA transmittal number. For example, to find the Carriers Manual, Part 3—Claims Process (HCFA-Pub. 13–3) transmittal entitled "Essential Access Community Hospital and Rural Primary Care Hospital", use the Superintendent of Documents No. HE 22.8/6, and the HCFA transmittal number 1626.

VI. General Information

It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer general questions concerning these items. Copies are not available through the contact persons. Copies can be purchased or reviewed as noted above.

Questions concerning Medicare items in Addenda III may be addressed to Margaret Cotton, Issuances Staff, Health Care Financing Administration, Room 688 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, Telephone (410) 966–5260.

Questions concerning Medicaid items in Addenda III may be addressed to Pat Prete, Medicaid Bureau, Office of Medicaid Policy, Health Care Financing Administration, Room 233 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, Telephone (410) 966–3246.

Questions concerning items in Addenda V may be addressed to Walter Rutemueller, Office of Coverage and Eligibility Policy, Health Care Financing Administration, Room 401 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, Telephone (410) 966–5395.

Questions concerning all other information may be addressed to Michael Robinson, Office of Regulations, Health Care Financing Administration, Room 132 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, Telephone (410) 966–5633.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, Program No. 93.774, MedicareSupplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: December 19, 1994.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Addendum I

This addendum lists the publication dates of the quarterly listing of program issuances and coverage decision updates to the Coverage Issues Manual.

March 20, 1990 (55 FR 10290) February 6, 1991 (56 FR 4830) July 5, 1991 (56 FR 30752) November 22, 1991 (56 FR 58913) January 22, 1992 (57 FR 2558) March 16, 1992 (57 FR 9127) June 11, 1992 (57 FR 24797) October 16, 1992 (57 FR 47468) January 7, 1993 (58 FR 3028) March 31, 1993 (58 FR 16837) July 9, 1993 (58 FR 36967) September 1, 1993 (58 FR 46200) December 22, 1993 (58 FR 67796) March 17, 1994 (59 FR 12610) August 5, 1994 (59 FR 40038) November 14, 1994 (59 FR 56501)

Addendum II—Description of Manuals, Memoranda, and HCFA Rulings

An extensive descriptive listing of Medicare manuals and memoranda was published on June 9, 1988, at 53 FR 21730 and supplemented on September 22, 1988, at 53 FR 36891 and December 16, 1988, at 53 FR 50577. Also, a complete description of the Medicare Coverage Issues Manual was published on August 21, 1989, at 54 FR 34555. A brief description of the various Medicaid manuals and memoranda that we maintain was published on October 16, 1992, at 57 FR 47468.

Medicare End Stage Renal Disease; Network Organizations Manual

This manual presents technical instructions and/or changes in procedures that pertain to ESRD network organizations in an understandable format, which can be easily modified. This manual benefits both HCFA and its customers.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 1994

Trans. No. Manual/Subject/Publication No.

Intermediary Manual Part 2—Audits, Reimbursement Program Administration (HCFA-Pub. 13–2) (Superintendent of Documents No. HE 22.8/6–1)

Beneficiary Services.
 Provider Services.

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Quarterly Periodic Interim Payment Report.

Intermediary Manual Part 3—Claims Process (HCFA-Pub. 13–3) (Superintendent of Documents No. HE 22.8/6)

Essential Access Community Hospital and Rural Primary Care Hospital.
 Criteria and Payment for Essential Access Community Hospital and Rural Primary Care Hospital.
 Review of Form HCFA–1450 for Inpatient and Outpatient Bills for Rural Primary Care Hospitals.
 Monthly Intermediary Workload Report. (Form HCFA–1566)—General.

Monthly Intermediary Workload Report. (Form HCFA-1566)—General.
 Completing Page One of the Monthly Intermediary Workload Report.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 1994—Continued

Trans. No.	o. Manual/Subject/Publication No.							
		Checking Reports.						
		Body of Report.						
1628	•	Payment for Blood Clotting Factor Administered to Hemophilia Inpatients.						
		Reporting Outpatient Services Using HCFA Common Procedure Coding System. HCPCS Codes for Diagnostic Services and Medical Services.						
		Ambulance Services.						
1629	•	Surgical Dressings, and Splints, Casts, and Other Devices Used for Reduction of Fractures and Dislocations.						
1630	•	Requirements for Submission of EMC Data.						
		File Specifications, Records Specifications, and Data Element Definitions for EMC Bills.						
		National Standard Electronic Remittance Advice.						
1631		Medicare Standard Electronic PC-Print Software. Medical Review Guidelines for Review of Observation and Assessment and Management and Evaluation in Skilled Nursin						
1001	•	Facilities.						
1632								
1633	•	HCPCS for Hospital Outpatient Radiology Services and Other Diagnostic Procedures.						
1634	•	Epoetin.						
1635	•	Medical Review of Home Health Services.						
		HCFA-485—Home Health Certificate and Plan of Care Data Elements. HCFA-486—Medical Update and Patient Information.						
		Carrier Manual Part 3—Claims Process (HCFA-14-3) (Superintendent of Documents No. HE 22.8/7)						
1489	•	Completion of Items on Page One of Form HCFA-1565.						
		Part D(2)—Claims Processing Timeliness—EMC Claims and Adjustments for CPEP CPT Calculations. Checking Reports Prior to Submittal to HCFA.						
1490	•	Epoetin.						
1491	•	Billing for Physician Assistant, Nurse Practitioner, or Clinical Nurse Specialist Services.						
		Billing for SNF and NF Visits.						
1492	•	Technical Specifications of the EOMB and Exhibits.						
1493	•	Type of Service.						
1494	•	Coding Physician Specialty. Coding Type of Supplier and Nonphysician Provider.						
		Coding Types of Service for Group Practice Prepayment Plan.						
		Description of Entry Code.						
1495	•	Therapeutic Shoes for Individuals With Diabetes.						
1496	•	Ambulatory Surgical Center Code.						
1497	•	Medical Review.						
		Coordination With Carrier Medicare Fraud Unit.						
		Development of MR Policy—General. National Coverage Policy.						
		Local MR Policy.						
		Internal MR Guidelines.						
		The Carrier Advisory Committee.						
		Data Analyses to Focus MR.						
		Aberrancies.						
		Taking Corrective Actions on Identified Aberrancies.						
		Conducting Evaluation of Effectiveness of Corrective Action. Standard Postpayment Data Reports.						
		Medicare FMR Status Report.						
		Provider Tracking System.						
		Prepayment Review Procedures.						
		Prepayment MR and Audit Trail.						
		MR Prepayment Screens.						
		Evaluation of MR Prepayment Screens.						
		Categories of MR Screens. MR Screen Parameters.						
		Developing Cases for Additional Medical Necessity Documentation.						
		HCFA Mandated and HCFA Optional MN Screens.						
		Prepayment Review Personnel and Procedures Levels of Manual Review.						
		Postpayment MR.						
		Postpayment Review Personnel.						
		Provider Audit List.						
		Comprehensive Medical Review Requirements. CMR Case Selection.						
		Conducting the CMR.						
		CMR Corrective Actions.						
		Overpayment Assessment.						
		Definition of Overpayment Assessment Terms.						
		Assessing an Overpayment When the CMR Was Based on a Statistically Valid Random Sample.						
		Assessing on Overpayment or a Potential Overpayment When the CMR Was Based on a Limited Sample/Subsample.						
		Comparative Performance Report Requirements.						
		MR Denials.						

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 1994—Continued

Trans. No.	Manual/Subject/Publication No.
1498 1499	Section 1879 Determination. Section 1870 Determination. Section 1842(I) Determination. Appeal of MR Denials. The Carrier Medical Director. Foot Care and Supportive Devices for Feet. Data Sets and Formats for Electronic Media Claims and Electronic Remittance Advice. Medicare Standard PC-Print-B Software.
1500	Epoetin.
	Program Memorandum Intermediaries (HCFA-Pub. 60A) (Superintendent of Documents No. HE 22.8/6–5)
A-94-5	 Letter to Participating Hospitals Regarding Physician Acknowledgment Statements Under the Physician Attestation Require ment.
A-94-6 A-94-7	 Medicare Payment for Extracorporeal Photopheresis Performed in Hospital Outpatient Setting. Hospital Outpatient Procedures: Update to List of Radiology Procedures and Other Diagnostic Services Subject to the Payment Limit and Update to the List of HCPCS Codes to Be Grossed-Up.
	Program Memorandum Carrier (HCFA-Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)
B-94-4 B-94-5	 Suspension of Beneficiary Address Overlay Process. Beneficiary Address Overlay.
	Program Memorandum Intermediaries/Carriers (HCFA-Pub. 60 A/B) (Superintendent of Documents No. HE 22.8/6-5)
AB-94-4 AB-94-5 AB-94-6	 Current Status of Medicare Program Memorandums and Letters Issued Before. Coverage of Oral Cancer Drugs and Uniform Coverage of Off-Label Uses of Anti-Cancer Drugs Provided for by Omnibus Budget Reconciliation Act of 1993. HCPCS Codes for Ambulance Services Furnished to Beneficiaries With End Stage Renal Disease and For Scheduled Trans ports.
	Program Memorandum Regional Offices General (HCFA-Pub. 51) (Superintendent of Documents No. HE 22.8/6–5)
94–2	Bed-Hold Policies for Long Term Care Facilities.
	Program Memorandum Medicaid State Agencies (HCFA-Pub. 17) (Superintendent of Documents No. HE 22.8/6–5)
94–6 94–7	 Current Status of Medicaid Program Memorandum and Action Transmittals Issued Before Calendar Year 1994. Title XIX, Social Security Act, Tuberculosis-Related Services.
P	rogram Memorandum Insurance Commissioners (HCFA-Pub. 80) (Superintendent of Documents No. HE 22.28/5:90-1)
94–2	Medigap Bulletin Series (Number Two).
	Regional Office Manual Medicare (HCFA-Pub. 23–2) (Superintendent of Documents No. HE 22.28/5:90–1)
327	The Contractor Performance Evaluation Program. CPEP Principles. Scheduling Reviews. CPEP Review Completion Dates. Sampling Methodology. Sampling Techniques. Sample Size Chart. Methodology For Determining Whether Performance Requirements Are Met. Determinations through Sampling. Documentation of CPEP Reviews. Program Requirements Criterion CPEP Review Report. CPEP Review Report. Process Improvement Criterion Documentation. Retention of Documentation. Notifying Contractors of CPEP Evaluation Results. Process Improvement Criterion. Appeals. Appeals Rights. Processing Appeals. Reporting Final Determination. Corrective Action Plan. When CAPs are Required. The Content of the CAP. CPEP Evaluation of Multi-State and Multi-Regional Contractors. Determining When Separate CPEPs are Needed.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 1994—Continued

Trans. No.

Manual/Subject/Publication No.

Definitions of Multi-Regional and Multi-State Contractors.

Principles of Evaluation of Multi-State Contractors and Multi-Regional Contractor FOs.

Separate Evaluation of the Program Requirements Criterion CPEP Standards.

Separate Evaluation of the Process Improvement Criterion of CPEP.

Evaluation of Financial Standards.

Sampling for Multi-State Contractors.

Reporting Requirements for Multi-State Contractors.

Contract Management Actions.

Peer Review Organization Manual (HCFA-Pub. 19) (Superintendent of Documents No. HE 22.8/15)

38 Background.

Confidentiality Requirements.

Report Requirements.

Publication Requirements.

Distribution Requirements.

Introduction.

Requirements.

Qualifications.

Additional Clinical Coordinators.

Responsibilities.

Cooperative Project Development and Implementation.

39 Hearings by an ALJ.

Appointment of Representative.

Foreword, Statutory/Regulatory References.

Notification of Quality Concerns to Affected Parties.

Confidential Information.

Hospital Manual (HCFA-Pub. 10) (Superintendent of Documents No. HE 22.8/2)

PRO Monitoring of Hospital Notices for Denial of Continued Stay of Inpatient Care Under PPS. 667

Issuance of Notices of Noncoverage.

Content of Hospital-Issued Notices of Noncoverage.

PRO Monitoring of HINNs.

Notices in Investigational/Experimental Procedures Situations.

Beneficiary Liability.

Provider Liability.

Right to a Reconsideration.

668 Surgical Dressing, and Splints, Casts, and Other Devices Used for Reduction of Fractures and Dislocations. 669

Data Elements on the UB-2.

Oral Cancer Drugs.

Billing for Clinical Diagnostic Laboratory Services Other Than To Inpatients.

Reporting Outpatient Surgery and Other Services.

Billing for Durable Medical Equipment and Orthotic/Prosthetic Devices.

Payment for Blood Clotting Factor Administered to Hemophilia Inpatients.

Payment for Epoetin. 670

HCPCS for Hospital Outpatient Radiology Services and Other Diagnostic Procedures.

Reporting Outpatient Surgery and Other Services.

Reporting Outpatient Surgery and Other Services.

672 Epoetin.

Christian Science Sanatorium Hospital Manual Supplement (HCFA-Pub. 32) (Superintendent of Documents No. HE 22.8/2-2)

33 Billing Procedures—General.

Billing Procedures Applicable to Periodic Interim Payment Method of Payment for Hospitals and SNFs.

Inpatient Admission and Billing Christian Science Sanatorium (Form HCFA-1450).

Completion of Form HCFA-1450 For Inpatient Christian Science Sanatorium Services or Christian Science Sanatorium Services

Claims Processing Timeliness.

Skilled Nursing Facility (HCFA-Pub. 12) (Superintendent of Documents No. HE 22.8/3)

330 Surgical Dressings, and Splints, Casts, and Other Devices Used for Reduction of Fractures and Dislocations. 331

Completion of Form HCFA-1450 for Inpatient and/or Outpatient Billing.

Provider Electronic Billing File and Record Formats.

Alphabetic Listing of Data Elements.

Health Maintenance Organization/Competitive Medical Plan Manual (HCFA-75) (Superintendent of Documents No. HE 22.8/21:989)

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ADDE	NDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 1994—Continued
Trans. No.	Manual/Subject/Publication No.
	Conditions for HCFA Approval of Novation Agreement. Leasing of HMO/CMP Facilities. Model Novation Agreement.
	State Medicaid Manual Part 3—Eligibility (HCFA-Pub. 45–3) (Superintendent of Documents No. HE 22.8/10)
63	Medicaid Estate Recoveries.
	Coverage Issues Manual (HCFA-Pub. 6) (Superintendent of Documents No. HE 22.8/14)
71	Outpatient Diabetic Education Programs.
	Provider Reimbursement Manual Part 1—(HCFA-Pub. 15–1) (Superintendent of Documents No. HE 22.8/4)
378	 Inpatient Routine Service Cost Limits for Skilled Nursing Facilities. Provider Requests Regarding Applicability of Cost Limits. Request for Exception to SNF Cost Limits. Adjustment of Interim Rate. Operational Review. Formal Appeal of Determinations on Requests for Reclassification, Exceptions, and Exemptions.
379	 Non-PPS Hospitals and Distinct Part Units. Hospitals and Distinct Part Units of Hospitals Subject to Rate of Increase Ceiling on Inpatient Operating Costs. Calculating Rate of Increase Ceiling on Hospital Inpatient Operating Costs. Exemptions From Rate of Increase Ceiling. Adjustments to Rate of Increase Ceiling Assignment of New Base Period. Appeal Rights.
Provi	der Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions (HCFA-Pub. 15–IIAC) (Chapter 29) (Superintendent of Documents No. HE 22.8/4)
2	 Worksheet C—Determination of Medicare Payment. Supplemental Worksheet B-1—Calculation of Pneumococcal and Influenza Vaccine Cost. Rounding Standards for Fractional Computations.
Provi	der Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions (HCFA-Pub. 15–IIAB) (Chapter 28) (Superintendent of Documents No. HE 22.8/4)
5	 General. Acronyms and Abbreviations. Worksheet S-2—Hospital and Hospital Health Care Complex Identification Data. Worksheet C, Parts III-V. Supplemental Worksheets M-1—M-4 Electronic Reporting Specifications for Form HCFA-2552-92.
Prov	ider Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions (HCFA-Pub. 15–IIX) (Chapter 24) (Superintendent of Documents No. HE 22.8/4)
6	Updated Graduate Medical Education Adjustment Factors for the 1989 Cost Reports.
Re	enal Dialysis Facility Manual (Non-Hospital Operated) (HCFA-Pub. 29) (Superintendent of Documents No. HE 22.8/13)
69 70	 Surgical Dressings, and Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations. Epoetin.
	Home Health Agency Manual (HCFA-Pub. 11) (Superintendent of Documents No. HE 22.8/5)
270 271 272	 Billing for Oral Cancer Drugs. Surgical Dressings, and Splints, Casts, and Other Devices Used for Reduction of Fractures and Dislocations. Data Elements Needed to Render a Home Health Coverage Determination. HCFA-485 Home Health Certificate and Plan of Care. HCFA-486 Medical Update and Patient Information.
Health Ma	ntenance Organization/Competitive Medical Plan Manual (HCFA-Pub. 75) (Superintendent of Documents No. HE 22.8/21:989
13	Effect of Change Without Novation Agreement. Submittal of Novation Agreement. Conditions for HCFA Approval of Novation Agreement. Leasing of HMO/CMP Facilities. Model Novation Agreement.

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ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 1994—Continued

Trans. No. Manual/Subject/Publication No.

End Stage Renal Disease Network Organizations Manual (HCFA-Pub. 81) (Superintendent of Documents No.

1 Authority. Purpose of Networks. Network Responsibilities. Health Care Financing Administration's Role.

Medicare/Medicaid Sanction—Reinstatement Report

94-7 Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers.

94-8 Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers.

Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated. 94–9 94-10

Cumulative Report of Physician/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated. Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated. 94-11

Publication date	Vol. 50 FR page numbers	CFR part	File code*	Regulation title	End of com- ment period	Effective date
07/13/94	35664	421	BPO-111-N	Medicare Program; Intermediary and Carrier Functions.	10/11/94	
07/14/94	35933–35935		BPO-116-FN	Medicare Program; Data, Standards, and Methodology Used To Establish Fiscal Year 1994 Budgets for Fiscal Intermediaries and Carriers.	07/14/94	
07/14/94	35935–35936		BPD-799-GN	Medicare Program; Medicare Secondary Payer (MSP) Amendments.		08/15/94
07/15/94	36069–36071	405, 414	BPD-770-CN	Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1994 (CORRECTION TO A FINAL RULE).		01/01/94
07/15/94	36072–36087	417, 431, 434, 1003.	RIN0991-AA44	Medicare and State Health Care Programs; Fraud and Abuse, Civil Money Penalties and Intermediate Sanctions for Certain Violations by Health Maintenance Organizations and Competitive Medical Plans.		09/13/94
07/18/94	36415–36418	421	BPO-105-P	Medicare Program; Part B Advance Payments to Suppliers Furnishing Items or Services under Medicare Part B.	9/16/94	
07/18/94	36419–36421	440	MB-085-P	Medicaid Program; Nurse-Midwife Services.	9/16/94	
07/19/94	36707–36713	412, 413, 418	BPD-436-F	Medicare Program; Periodic Interim Payments for Hospitals and Other Providers.		08/18/94
07/25/94	37702–37720	435, 440, 441	MB-008-FC	Medicaid Program; Home and Com- munity-Based Services and Res- piratory Care for Ventilator-Depend- ent Individuals.	09/23/94	08/24/94
08/02/94	39296–39298	400	OFH-017-FC	Medicare and Medicaid Programs; Approved Information Collection Requirements.	10/03/94	08/02/94
08/04/94	39828–39830	405, 414	BPD-770-CN	Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1994 (OFR CORRECTION TO A FINAL RULE).		07/15/94
08/05/94	40037–40038		OMC-020-N	Health Maintenance Organizations; Qualification Determinations During the Period January 1, 1994 through March 31, 1994.		
08/05/94	40038–40048		BPO-126-N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Deci-		
08/22/94	43050–43053	435, 436	MB-001-F	sions-First Quarter 1994. Medicaid Program; Eligibility and Coverage Requirements.		08/18/94

Publication date	Vol. 50 FR page numbers	CFR part	File code*	Regulation title	End of com- ment period	Effective date
08/26/94	44097–44109	412, 413, 414	BPD-763-P	Medicare Program; End Stage Renal Disease (ESRD) Payment Excep- tion Requests and Organ Procure- ment Costs.	10/25/94	
08/26/94	44151–44152		OPL-001-N	Medicare Program; Meeting of the Practicing Physicians Advisory Council.		
09/01/94	45330–45524	412, 413, 466, 482, 485, 489.	BPD-802-FC	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1995 Rates.	10/31/94	10/01/94
09/06/94	46056–46057		BPO-117-GN	Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance During FY 1994.		09/06/94
09/07/94	46258–46263		BPO-123-GNC	Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance During FY 1995.	10/07/94	10/01/94
09/08/94	46500–46517	405, 482, 485	BPD-646-IFC	Medicare and Medicaid Programs; Conditions of Coverage for Organ Procurement Organizations.	11/07/94	10/11/94
09/23/94	48805–48811	435, 436	MB-052-IFC	Medicaid Program; Outstation Intake Locations for Certain Low-Income Pregnant Women, Infants, and Children Under Age 19.	11/22/94	10/24/94
09/23/94	48811–48825	456	MB-050-F	Medicaid Program; Drug Use Review Program and Electronic Claims Management System for Outpatient Drug Claims.		10/24/94
09/27/94	49249–49251		ORD-069-N	Medicaid Program; Demonstration Proposals Pursuant to Section 1115(a) of the Social Security Act; Policies and Procedures.		
09/30/94	49826–49834	405, 410, 411, 413, 494.	BPD-724-F	Medicare Program; Medicare Coverage of Screening Mammography.		10/01/94
09/30/94	49834–49843	417	OMC-009-FC	Medicare Program; Qualified Health Maintenance Organizations: Technical Amendments.	11/29/94	10/31/94

^{*}GN—General Notice; PN—Proposed Notice; FN—Final Notice; P—Proposed Rule; F—Final Rule; FC—Final Rule with Comment Period; CN—Correction Notice; N—Suspension Notice; WN—Withdrawal Notice; NR—Notice of HCFA Ruling; IFC—Interim Final Rule with Comment Period.

Addendum V—Medicare Coverage Issues Manual

(For the reader's convenience, new material and changes to previously published material are in italics. If any part of a sentence in the manual instruction has changed, the entire line is shown in italics. The transmittal includes material unrelated to revised sections. We are not reprinting the unrelated material.)

Transmittal No. 71; section 80–2 Outpatient Diabetic Education Programs. NEW IMPLEMENTING INSTRUCTIONS— EFFECTIVE DATE: Services Furnished on or After 09/22/94.

Section 80–2, Outpatient Diabetic Education Programs.— This section has been added to reflect coverage of outpatient diabetic education programs.

80–2 OUTPATIENT DIABETIC EDUCATION PROGRAMS

An outpatient hospital diabetic education program is a program which educates patients in the successful self-management of diabetes. An outpatient diabetic program includes education about performance of frequent self-monitoring of blood glucose,

education about diet and exercise, an insulin treatment plan developed specifically for the patient who is insulin-dependent, and motivation to use the skills learned to enable self-management. Education programs should identify themselves as programs for non-insulin patients, insulin-dependent patients, or both.

Outpatient hospital diabetic education programs may be covered under Medicare provided the services are furnished under a physician's order by the provider's personnel and under medical staff supervision to individuals who are registered patients of that provider. The services must be closely related to the care and treatment of the individual patient and must provide the patient with essential knowledge that aids in the patient's active participation in his/her own treatment and the skills that enable self-management.

Do not substitute formally structured education programs for the more traditional and generally effective instruction included as a part of the basic care and treatment furnished to the patient by the health care professional.

The overall goal of outpatient hospital diabetic education programs is self-management of the disease, and each program must be sufficiently flexible to meet the individual needs of the patient. (This does not preclude some sessions of the programs to be given on an outpatient group basis.) The individual plan of care must indicate at a minimum the goals for the individual patient and how these goals will be realized.

Not all diabetic patients are eligible to participate in these programs. In general, the kinds of patients that are likely to be suitable candidates for outpatient education programs are newly diagnosed diabetics and/or unstable diabetics (e.g., a long-term diabetic with current management problems).

Entrance into these programs is by physician referral only. Self-referral is not covered. The duration of these programs should be sufficient to meet the goals of self-management within the timeframe indicated in the plan of treatment. It is not expected that any given patient could be eligible to reenter an education program unless new conditions warrant it.

After the intermediary determines that a program may be covered, the intermediary may request additional documentation to make a claims determination.

[FR Doc. 94–32295 Filed 12–30–94; 8:45 am] BILLING CODE 4120–03–P

Public Health Service

Office of the Assistant Secretary for Health; Availability of Grants for Minority Community Health Coalition Demonstration Projects.

AGENCY: Office of Minority Health, Office of the Assistant Secretary for Health, USPHS, DHHS.

ACTION: Notice of Availability of Funds and Request for Applications for Minority Community Health Coalition Demonstration Project Grants (Coalition Outreach Grants).

AUTHORITY: This program is authorized under section 1707(d)(1) of the Public Health Service Act, as amended in Public Law 101–527.

PURPOSE: The OMH announces the availability of grants to provide support to minority community health coalitions to develop, implement, and conduct demonstration projects which coordinate integrated community-based screening and outreach services and include linkages for access and treatment, to minorities in high risk, low income communities. These projects are to address socio-cultural and linguistic barriers to care and should have the potential for replication in similar communities.

APPLICANT ELIGIBILITY: Eligible applicants are public and private nonprofit organizations which will serve as the grantee organization for a coalition which has a history of OMH coalition grant support. This means prior support under: the Minority Community Health Coalition Demonstration Grant Program; the Minority Male Demonstration Grant Program (Intervention or Coalition Development); the Hispanic/Latino Community Health Coalition Development Project Grants; and the OMH/HRSA AIDS Coalition grants funded under the Rural Health Outreach for AIDS Education grants and Health Care Services for Residents of Public Housing. In most cases the applicant organization will be the same organization that served as the grantee on the original OMH grant. However, in a few instances: (1) The coalition has become a free standing entity, or (2) another member of the coalition has been designated to serve as the lead, grantee agency. In this case, the application must include a letter from

the original grantee organization verifying that the new applicant organization is a member of the coalition and is now designated to serve as lead for the same coalition which received prior OMH support. Only one application shall be submitted on behalf of any eligible coalition.

Applicant coalitions must include a health care facility such as a community health center, migrant health center, health department or medical center. The coalition should have the capacity to plan and coordinate services which reduce existing socio-cultural barriers. Specifically, the coalition will be called upon to carry out screening, outreach and enabling services to ensure that clients follow up with treatment and treatment referrals.

In order to verify that a viable coalition exists, the following must be provided: (1) The grant number of the prior OMH grant, (2) a concise narrative history of the existing minority community health coalition; (3) a copy of the coalition's mission statement and organizational chart; current membership roster indicating the race/ ethnicity and roles of each coalition member organization; and (4) a dated copy of the founding bylaws or memorandum of agreement, and recent minutes or equivalent documents as proof that the coalition has been viable and operational over a sustained period.

Background

In prior fiscal years, the Office of Minority Health has focused on the establishment and enhancement of minority coalitions. Many coalitionconducted interventions included provision of health assessments and screening as an approach to improving the health of the targeted communities. Consistent with the broader public health experience, OMH found that many programs needed to go beyond provision of screening to provision of more systematic follow-up for access and treatment. Therefore, in FY 1995, OMH's coalition grants will focus on projects that address socio-cultural barriers and that will demonstrate effective coordination of integrated community-based screening, outreach and other enabling services thus insuring linkage to treatment or other indicated follow-up.

ADDRESSES/CONTACTS: Applications must be prepared on Form PHS 5161–1 (Revised July 1992). Application kits and technical assistance on budget and business aspects of the application may be obtained from Ms. Carolyn A. Williams, Grants Management Officer, Office of Minority Health, Rockwall II Building, Suite 1000, 5515 Security

Lane, Rockville, MD, 20852, (telephone 301/594–0758). Completed applications are to be submitted to the same address.

Technical assistance on the programmatic content for the Coalition Grants may be obtained from Ms. Joan S. Jacobs. She can be reached at the Office of Minority Health, Rockwall II Building, Suite 1000, 5515 Security Lane, Rockville, MD 20852, (telephone 301/594–0769) or by Interest E-mail [Jacobs OASH.SSW.DHHS.GOV].

In addition, OMH Regional Minority Health Consultants (RMHCs) are available to provide technical assistance. A listing of the RMHCs and how they may be contacted in provided in the grant application kit. Applicants also can contact the OMH Resource Center (OMH/RC) at 1–800/444/6472 for health information and generic information on preparing grant applications.

DEADLINE: To receive consideration, grant applications must be received by the Grants Management Officer by March 6, 1995. Applications will be considered as meeting the deadline if they are either: (1) Received at the above address on or before the deadline date and received in time for orderly processing. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted in lieu of a postmark. Private meeting postmarks will not be accepted as proof of timely mailing. Applications which do not meet the deadline will be considered late and will be returned to the applicant unread.

AVAILABILITY OF FUNDS: It is anticipated that in Fiscal Year 1995, the Office of Minority Health will have approximately \$2.0 million available to support approximately 14 awards of up to \$150,000 each under the Minority Community Health Coalition Grant Program.

PERIOD OF SUPPORT: Support may be requested for a total project period not to exceed 3 years. Non competing continuation awards will be made subject to satisfactory performance and availability of funds.

PROJECT BUDGETS: Budgets of up to \$150,000 total direct and indirect costs per year may be requested to cover: The cost of personnel; consultants; support services; materials; and travel. Project budget must include travel for one project staff member to meet with the OMH Coalition Grant Program Director in Washington, DC. Funds may not be used for building alternations, renovations, or to purchase equipment except as may be acceptability justified in relation to conducting the project activities. Funds are to be used to